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# More-than-national and lessthan-global: The biochemical infrastructure of vaccine manufacturing

Nele Jensen <sup>(D)</sup>, Andrew Barry <sup>(D)</sup> and Ann H. Kelly <sup>(D)</sup>

## Abstract

The recent efforts to mount an R&D response to public health emergencies of international concern have led to the formation of what we term a biochemical infrastructure of vaccine development and production. In principle, this infrastructure is expected not only to curtail existing pandemics but also anticipate and contain yet-to-emerge future threats. Critically, by nature of its geographical distribution and technical modularity, that infrastructure promises both to accelerate and expand access to essential medical tools, and in so doing, redress global health inequities. In practice, however, the biochemical infrastructure of vaccines remains highly uneven, fragmented and unjust. Moving beyond calls for 'global health solidarity', this paper examines the key actors, normative techniques and socio-technical assemblages, from viral platform technologies to intellectual property waivers and from accelerated regulatory pathways to advance market commitments, that serve to link 'just-in-case' and 'just-in-time' modalities of

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global health R&D. We argue that the biomedical infrastructure of vaccine development and production emerging in the wake of the COVID-19 pandemic is unfolding across an innovation ecosystem that is more-than-national and yet less-than global: a reconfiguration that may offer possibilities for a new, radically-overhauled, model of vaccine equity.

Keywords: vaccine R&D; COVID-19; biochemical engineering; infrastructure; equity.

When we open a bottle of medicine and consume its contents, we connect ourself to forces far beyond us. (Gabriel, 2014, p. 1)

# Introduction

The pace of COVID-19 vaccine development has been nothing short of remarkable. In under a year from when the virus was first sequenced, millions around the world had received one of many viable vaccine candidates. By mid-April 2021, as key global health representatives logged into *Expanding Africa's vaccine manufacturing for health security*, a virtual conference co-hosted by African Union and the Africa Centres for Disease Control and Prevention (Africa CDC), 710 million vaccine doses had found their way into arms (Mathieu *et al.*, 2021). And yet this tremendous global health success was tempered by the fact that only 2 per cent of those vaccinations had been administered on the African continent, with many countries still awaiting the bulk of vaccine doses they had been allocated under the global vaccine-sharing initiative COVAX (Cascais, 2021; Safi & Kirk, 2021).

Framed by this stark disparity, the event began with a pledge by Africa CDC to increase the share of vaccines produced domestically dramatically from 1 per cent to 60 per cent by 2040. This ambition was underlined by the ceremonial signing of a Memorandum of Understanding with the Coalition for Epidemic Preparedness Innovations (CEPI) to develop infrastructure and expertise in vaccine manufacturing across the African continent. For Africa CDC's director John Nkengasong, the MOU represented a first step towards a proposal for 'A New Public Health Order' to reconfigure the emergency response system in Africa and future proof equitable access to health technologies through the strengthening of domestic pharmaceutical manufacturing and regulatory capacity (Nkengasong & Tessema, 2020). For CEPI, as CEO Richard Hatchett noted, the MOU signalled a 'paradigm-shift' for global health innovation, as R&D efforts expand their concerns from the development of specific biomedical products to fostering a more distributed research & development (R&D) ecosystem (Hatchett, 2021). To some of those in attendance, the event seemed nothing short of an attempt to 'plot a vaccines revolution' (Irwin, 2021a).

The apotheosis of biomedical triumphalism, vaccines are thought to provide the ultimate answer to imminent and impending global public health predicaments - an immunitary imaginary of security achieved through the eradication of threats (Ajana, 2021; Beisel, 2017; Brown, 2019; Heller 2021; Leach & Fairhead, 2007; Patchin, 2020). Leaving aside for a moment longstanding social science critique of 'magic bullet' solutionism (e.g. Cueto, 2007), the COVID-19 pandemic has also exposed the gaps in the systems that need to be in place even before vaccines have to prove their workability in practice. Multilateral initiatives to ensure widespread vaccine access such as advance market commitments (AMC), pool procurement schemes and 'fair' vaccine allocation frameworks have been bedevilled by logistical constraints, systemic inequalities, poorly articulated regulatory frameworks, as well as sovereign claims over vaccine production, raw materials and supply chains. Even as the threat COVID-19 poses to global health security gradually fades from view, the failures of equitable vaccine access remain glairing - and, as we will argue, attest to the fundamental inadequacies of the contemporary model of global health innovation.

In this paper, we develop the notion of a more-than-national, yet less-thanglobal biomedical infrastructure as, at once, illustrative of the geographical distortion of the current vaccine R&D landscape, and as a conceptual tool to explore just how the COVID-19 pandemic might precipitate a critical transition in health innovation and manufacturing towards local vaccine contingencies. Our contention is that the shape of more-than-national, less-than-global assemblages is not predetermined (cf. Deleuze, 1986; Ong & Collier, 2005), and that the call for a New Public Health Order is a performative intervention: it points at once to the existence of a public health emergency response system that is highly fragile, fragmented and inadequate to ensure equitable access to novel biomedical technologies – and to the possibility of its inventive reimagination.

Our analysis of an emerging more-than-national biochemical infrastructure develops from a rich tradition in science and technology studies (e.g. Barry, 2001; Star, 1999; Star & Ruhleder, 1996). In broad strokes, this work has sought to refashion infrastructures as complex entanglements of people, materials, practices and norms whose exposition allows revealing the 'real work of politics and knowledge production' (Bowker & Star, 1999, p. 34). This scholarship can be characterized by four important insights: first, that smoothly-operating infrastructures are those that are invisible (Star & Ruhleder, 1996); second, that infrastructures effect the foregrounding of some phenomena at the expense of others (Bowker & Star, 1999); third that metrological and regulatory infrastructures, or 'metrological zones', may be as important as 'physical' infrastructures of connectivity, such as railway lines and telecommunications networks (Barry, 2006); fourth, that infrastructures have been critical means through which the potential economic value of the future can be projected and captured in the present (Birch & Muniesa, 2020; Mitchell, 2020).

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The social lives and political liveliness of infrastructures has also provided a rich vein of analysis in anthropology, focusing critical attention to contexts where the smooth operation of technical systems cannot be assumed (e.g. Anand et al., 2018; De Boeck, 2011; Degani, 2017; Harvey & Knox, 2012; Larkin, 2013). Rather than the 'taken for granted' background of the built environment, infrastructures are often a feature of their vulnerability, generating civic capacities and economic value at moments of breakdown and through the labour of maintenance and repair (e.g. Degani, 2017; Fredericks, 2018). Ethnographic attention to infrastructural fragmentation and failure has further served to articulate the affective dimensions of those relational assemblages - the expectations, hopes and desires infrastructures carry with them, the promises they convey for national development and civic advancement, but also the frustrations they provoke as those aspirations give way to the neoliberal realpolitik of social privatization (Anand et al., 2018; Elyachar, 2010; Fredericks, 2018). Perhaps most salient for our case are those insights developed from ethnographic work on the endurance and degradation of biomedical infrastructures in sub-Saharan Africa that stand as a testament to both postcolonial aspirations of modernity, and the complex histories and shifting priorities of international health efforts on the continent (Geissler & Tousignant, 2016; Graboyes & Carr, 2016; Wendland, 2016).

Starting from postcolonial sites defined by uneven development, in these accounts, we see how infrastructures have been and are developed often in contravention to, if not at the expense of, public services (e.g. Harvey & Knox, 2012; Hetherington, 2014; Simone, 2004). It is that normative orientation that this paper hopes to extend to reflect critically on how vaccines might be better considered to address the needs of users and citizens (Honig, 2017). In this light, we take Nkengasong's call for a 'New Public Health Order' to imply that vaccines can be seen as part of a 'welfare critical' infrastructure of public goods and services - 'a foundational economy' that stretches beyond the boundaries of the nation-state.<sup>1</sup> In this regard, the geographic magnitude and economic scale of the COVID-19 pandemic has had a catalytic effect, highlighting the shortages and inequities that have bedevilled the response, as well as the unsustainability of a global pandemic preparedness system built on and rehearsing worn charitable models so prevalent in global health. More so, the response to the pandemic has exposed the blindspots attendant to the current infrastructures of innovation, which have systematically failed to prioritize manufacturing, investments in infrastructure, and the building of national and public regulatory and metrological zones. In short, the COVID-19 pandemic has highlighted the urgent need for 'investments in human capital ... and infrastructure' in vaccine R&D, which 'deepen the range of ruptures and transformations in .... economic practices' in Africa and beyond (Sarr, 2016, pp. 42–43).

Our argument explores the idea of a more-than-national, less-than-global biochemical infrastructure of vaccine production in three parts. First, we focus on the timescape of vaccine R&D, not only the operations of hope and

deferral that structure global health investment, but also the emphasis on the value of both acceleration and anticipation in R&D. Models of vaccine R&D have developed from the assumption that research is undertaken in anticipation of the pandemic to come, is *accelerated* as an emerging and shifting pandemic is recorded, and continues to be *adjusted* as the impact of vaccination is observed. Acceleration is not merely a matter of pace, but the conjunction of two previously distinct ecologies of emergency (Kelly, 2018) and preparedness (Lakoff, 2017): R&D just-in-case is brought together with just-in-time manufacturing. In this context, we point to the idea of the 'platform' as an increasingly central idea in biomedical R&D and manufacturing. Platform technologies point to a transition from bespoke vaccinology to assembly line - a new mode of production that promises to actualize just-in-time and just-in-case manufacturing. Following Keating and Cambrosio (2000), we thus treat 'the platform' not merely as an empirical object, but as an analytical tool to explore how these technologies may reconfigure 'more-than-national' and 'less-than-global' landscapes that contain multiple and overlapping biomedical infrastructures as technological zones, and new relations between international, national and local institutions.

In the second part of the paper, we examine more closely the set of competing and contradictory valuations - of fiscal costs, legal regulations, political judgements and moral virtues - that have shaped biomedical infrastructures. Attention to the dynamics of investment, maintenance, material and immaterial labour that extend infrastructures in space and project them into the future has underscored the importance of time to infrastructural capacity and generative power, and the role of infrastructures as instruments of both capitalization and colonial rule (Mitchell, 2020). We argue that the recent emphasis on strengthening local and regional vaccine manufacturing capacities marks a move away from a paradigm of 'global health' that promises the dissolution of national boundaries in the name of global cooperation and vaccine distribution (Koplan et al., 2009) and yet has sustained an uneven geography of vaccine production bolstered by intellectual property claims and driven by national interests. Here, vaccines provide a paradigmatic case, by pointing to the situated, socio-material labour and investment that belies even the most mobile of 'humanitarian devices' and the embodied precarities 'magic bullets' can leave in their wake (Collier et al., 2017).

In a third part, we further the case for conceiving of vaccines and vaccine platforms not just as objects but as elements of shifting infrastructural assemblages that engage with and generate multiple orders of value, and that are projected both spatially and temporally into the future. Vaccines represent, in Gabriel Hecht's (2018) terms, 'inter-scalar vehicles' that forge multiple connections between local and regional spaces. At the same time, they should not be thought of simply as commodities or public goods but as components in uneven biochemical infrastructures. Our contention is that equity, accountability and legibility are not just outcomes of technopolitical processes and negotiations but are always already enfolded within the emerging biomedical infrastructure

itself (Karim *et al.*, 2021). While the fastmoving modularity of the platform entails some risk – that infrastructures fail to ever touch ground and local contexts and concerns skipped, that local labour is rendered ever-more fungible and thus precarious – we see promise in the open-ended and *multisided* (rather than simply multisited) innovation ecosystem the platform enables. In this way, the platform promises not just to generate innovative vaccines but has the potential contribute to the invention of a different global public health order.<sup>2</sup>

# Anticipation and acceleration

According to conventional wisdom, vaccines do not make good markets. Vaccines are complex biological products, and they are difficult to devise, test and produce, making their development inherently slow and potentially costly (Beasley, 2015). Successful preventative vaccines against infectious diseases are also, by their very nature, a threat to their own existence: if they work well and are widely used, they likely become obsolete. For these reasons, vaccines tend to be less commercially attractive for manufacturers compared to curative treatments, more so if they are targeted at diseases considered to primarily affect poorer populations (Wouters *et al.*, 2021; Xue & Ouellette, 2020). As influential economists have argued, pharmaceutical firms are reluctant to invest in vaccines for diseases that affect low-income countries as 'they would not be able to sell the vaccine at prices that would cover their riskadjusted costs' (Kremer & Glennerster, 2004, p. 3).

The limited commercial attractiveness of vaccines has been cited as a key reason for why, until recently, several major pharmaceutical companies, including AstraZeneca, had largely withdrawn from vaccine development, while for others, including Pfizer, vaccines only formed a small fraction of their global sales. *The Economist* bemoaned in 2010 that for decades vaccines were a neglected corner of the pharmaceutical business, as old technologies, little investment, and abysmal profit margins had prompted many firms to sell their vaccine divisions to concentrate on more profitable drugs (*The Economist*, 2010).

And yet, new configurations of technologies, regulatory mechanisms and funds that have emerged to address the need for a rapid response have rendered these assumptions suspect: at the same time that innovations in vaccine development presage a significant cutback of R&D timelines and costs, a slew of innovative R&D financing mechanisms, such as up-front grants, investment tax credits, volume guarantees and advanced purchase agreements, serve to 'push' and 'pull' commercial vaccine development with promises of closing the gap between R&D investment and future profits, while corporate risks are increasingly absorbed by the state and international institutions.

In contrast to the the 'distributed innovation system' that has characterized drug development since the 1990s and 2000s (Cambrosio *et al.*, 2004; Mittra, 2016) and enabled accelerated drug development through high-capacity

screening, computer modelling and combinatorial chemistry (Barry, 2005), vaccine development has traditionally relied on far more low-tech techniques, typically the use of inactivated or modified forms of a disease-producing virus that elicit an immune response without causing illness. Operating according to a 'one-bug-one-drug' principle, developing new vaccines required years of laboratory and field research to identify suitable candidates and establish their immunogenicity and safety in animal models before an application for testing in human subjects can be made. And if successful, the development of a vaccine has typically proceeded in a linear fashion through sequential stages of clinical testing, licensure, manufacturing, marketing and post-marketing surveillance – each of which could prove lengthy, not least since vaccines are considered biological materials and thus subject to stringent and often time-consuming quality control and safety requirements.

The slow timelines of vaccine development - and the resistance to 'fasttracking' measures increasingly common in other fields of biomedical innovation - have only become more problematic in light of current orientations in global health R&D (e.g. Webster, 2019). Andrew Lakoff (2017) traces a 'new regime of public health preparedness' back to the 1990s and 2000s and a specifically US reaction to post-Cold War concerns about bioterrorism (p. 9). But over the past decade, a global logic of preparedness has been distended as a seemingly accelerating cycle of threats of pandemic proportions the 2009 H1N1 influenza pandemic, the 2012 MERS outbreak, the 2014-2016 West African Ebola outbreak, the 2015-2016 Zika epidemic, and now COVID-19 - has turned 'global health security' into a matter of international concern. As the focus has shifted beyond the amelioration of already existing disease patterns to encompass the anticipation of potentially fatal future outbreaks (Caduff, 2015; Lakoff, 2015), new modes of calculative and speculative vigilance are meant to enable a rapid response to the next contagious threat (Kelly, 2018).

The 2014–2016 West African Ebola epidemic marks a critical event both in the development of a global system of 'pandemic preparedness' and regional institutional innovations such as the formation of the Africa CDC (Nkengasong et al., 2017). Efforts to bring the largest and most-complex outbreaks of its kind to a halt entailed radically compressed late-stage R&D timelines and culminated and the deployment of experimental vaccine candidates. But a series of ex-post analyses nonetheless blamed a lack of speed and response coordination for the escalation of the outbreak (Moon et al., 2017; Piot et al., 2019). As part of efforts to address this apparent gap, a series of initiatives were launched to improve pandemic preparedness. For example, to streamline and guide global research into countermeasures, WHO started publishing a list of specific priority pathogens deemed most likely to cause the next pandemic through its Research and Development Blueprint initiative<sup>3</sup> (Kieny, 2018). Whereas the pre-selection of potentially hazardous pathogens served to prime a R&D system that could be quickly mobilized in response to an anticipated threat, further speculative efforts have been undertaken to prepare for the eventuality of an outbreak of a disease of yet unknown origins. The ominous-sounding 'Disease X' has been included in WHO's R&D Blueprint since 2018 to boost R&D preparedness for the known unknown – a disease that will cause a catastrophic outbreak in the future but whose origin, by its very nature, cannot be predicted in the present.

As a powerful signifier of the perceived ever-present threat of future pandemic catastrophe, the evocation of 'Disease X' has helped further boost R&D for so-called 'platform technologies' that are envisioned to be 'pathogen agnostic'. That is, research on vaccine technologies has come to focus less on the antigen *per se*, but rather on the mechanism used to deliver the antigen into bodies, in the hope that these mechanisms can be rapidly adapted to target any new emerging disease threat. In other words, by making use of specific standardized steps or components in the vaccine development and manufacturing process that may be utilized across a variety of pathogens, platform technologies are expected to displace the traditional 'one bug, one drug' approach in vaccinology with a 'plug-and-play' model that is rapidly adaptable in the face of novel threats. A powerful instantiation of what Wajcman and Dodd (2017) refer to as 'technologies of acceleration', vaccine platforms are speculative devices whose allure lies precisely in their promise to retain enough flexibility to be adaptable to future and yet unknown threats.

The COVID-19 response was the first time that the promise of such technology platforms materialized: it is the work on such platform technologies, especially mRNA and viral vector-based vaccines, that has received much of the credit for the record speed of the development of viable COVID-19 vaccines - regulatory approval of the first vaccines occurred within a year following the publication of the SARS-CoV-2 genomic sequence. As a Nature review noted, the ease of using a pathogen's genetic sequence to construct an antigenencoding segment and package it in a vaccine means that 'RNA vaccines seem built for speed' (Dolgin, 2021). The same could be said of adenovirus vector vaccines, with Oxford AstraZeneca's frontrunner COVID-19 vaccine ChAdOx1using SARS-CoV-2 genetic information that is 'plugged into' an existing chimpanzee adenovirus vector. Whereas nucleic acid vaccines were initially commercially developed primarily for therapeutic applications against cancer (Sahin et al., 2014), Oxford's work on the adenovirus vector platform was initiated precisely in response to the Ebola pandemic and the perceived threat of 'Disease X' (Gallagher, 2020). We return to consider further the significance of vaccine platforms in the final section of this paper.

Importantly, although technological innovation has played a critical part in the acceleration of vaccine R&D, delivering on the promise of significantly compressed timelines for moving vaccine candidates from the lab to the clinic has also required adjustments to other components of the R&D machinery, including to regulatory and financing mechanisms. In terms of the former, regulatory agencies, such as the US FDA, paved the way for accelerated COVID-19 vaccine approval procedures by, in principle, allowing pre-clinical research data for a vaccine platform – that is, not just a specific vaccine candidate but the delivery system – to be used to support Investigational New Drug (IND) applications (Krammer, 2020; US FDA, 2020). Furthermore, recent regulatory adjustments have enabled a new 'pandemic paradigm' of clinical testing (Lurie et al., 2020) that is marked by the staggering and overlapping of clinical trial phases, adaptive trial designs, 'fast-tracked' regulatory review, and the issuing of emergency use authorizations (US FDA, 2020). Such a compression of vaccine R&D timelines has also required the rapid mobilization of funds and an unprecedented level of coordination and collaboration between different state and non-state actors. In other words, novel vaccine technology platforms are but one component in an emerging biochemical infrastructure of vaccination whose defining feature is the ability to permutate in *perpetuity*, with the potential to being mobilized and adapted in response to not only novel pathogens, but also to known pathogens as they mutate - as has been the case with COVID-19 (Monrad et al., 2021, p. 1). A stable biomedical infrastructure is therefore one which provides the basis to evolve in response to changing conditions - its stability depends on its elasticity.

The strive for flexibility and speed has also been accompanied by a remarkable plasticity of a pharmaceutical innovation model based on the speculative calibration of financial risk and reward, as states, philanthropists and international organizations have increasingly taken on the role of reducing the risk for private capital. Not least due to the high risk of failure associated with successfully bringing vaccines to market and the uncertainty over market size, commercial incentives for pharmaceutical companies have long been considered significantly lower for preventative vaccines compared to treatments (Gouglas *et al.*, 2018; Kremer & Snyder, 2003; Plotkin *et al.*, 2017). In short, until recently, a common narrative was that without substantial state support, the prevalence of viruses in low-income countries could not provide the basis on which investors and pharmaceutical companies could project a sufficiently stable future on which they could capitalize (cf Mitchell, 2020).

Under a 'emergency paradigm', such risks arguably increase. After all, with the existing linear R&D model extensive data analysis occurred before moving a vaccine candidate into expensive later stage clinical trials, thereby both simultaneously increasing the cost but also minimizing the risk for private-sector pharmaceutical companies (Krammer, 2020; Lurie *et al.*, 2021). In contrast, as pandemic preparedness and emergency response emphasize the need for speed, the resulting higher costs and risks are claimed to require even further incentives and risk-sharing mechanisms to make emergency R&D attractive enough for commercial vaccine developers. That 'outbreaks are unsustainable markets' was one of the key take-aways of the WHO's response Zika emergency – an innovation effort bedevilled by the uncertainties of a continually evolving and epidemiologically elusive epidemic.<sup>4</sup> In these circumstances, the push for acceleration has been paralleled by the outsourcing of costs and risks to the state. In this 'post neoliberal' model, state intervention becomes critical for capital accumulation.

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CEPI, the Coalition for Epidemic Preparedness Innovations, is among the most prominent representatives of the re-articulation of state and corporate interests in the name of de-risking pandemic preparedness - and, together with the Africa CDC, one of Ebola's key legacies (Nkengasong et al., 2017). In response to post-Ebola litanies that diagnosed a 'fragile global system for outbreak prevention and response' and a need for novel funding avenues for commercially unattractive yet 'outbreak-relevant' drugs and vaccines (Moon et al., 2015, p. 2204), CEPI was launched in 2017 at Davos as a publicprivate partnership with the dual mission to compress R&D timelines by front-loading financing for and de-risking the development of innovative technologies for which commercial markets are considered uncertain - 'just in time': and to stimulate R&D and build stockpiles for pathogens as of yet unknown origins - 'just in case' (CEPI, 2021). CEPI's set-up as an explicitly 'global' public-private partnership seemingly embodied a new vaccine R&D model that emphasizes financial incentives and transnational and trans-sectoral collaboration as crucial levers of an emergency response system. At the same time, however, this system has remained markedly less-than-global by sustaining a distinctly uneven geographical distribution of vaccine R&D and manufacturing.

## Infrastructure and inequality

The COVID-19 pandemic has been a test case for the reforms undertaken to reconstruct the global system for outbreak prevention and response post-Ebola (cf. Morris, 2016). And indeed, many of the pandemic preparation and response mechanisms designed to coordinate and accelerate the development of countermeasures seem to have successfully kicked into gear and incentivized innovation: by April 2021, only 15 months into the pandemic, a handful of COVID-19 vaccines had achieved regulatory approval - many of which had received substantial financial backing from CEPI and/or national governments - and many high-income countries had successfully vaccinated a significant share of their national populations. More so, the COVID-19 Vaccines Global Access initiative (COVAX) had been operating for a year as a designated international coordinating mechanism to ensure rapid and equitable access to CEPIsupported, WHO-approved COVID-19 vaccines for low-and middle-income countries, leveraged through a so-called Advance Market Commitment (AMC) that incentivises vaccine manufacturers through a combination of pooled procurement and advance purchase commitments.

And yet, by April 2021, vaccine roll-out in many low-income countries had barely begun (McClellan *et al.*, 2021; Ritchie *et al.*, 2020). Only just over 30 million doses, or 2 per cent of the global vaccine supply, had reached the African continent (WHO AFRO, 2020). Not only had COVAX struggled to meet its funding target (BBC News, 2021), but the number of vaccines available for distribution had been significantly curtailed by high-income countries using

their financial power and role as major manufacturing bases to negotiate priority purchase agreements with leading vaccine manufacturers (*Nature*, 2021). Manufacturing delays, supply chain disruptions, and export restrictions – such as those that affected the Serum Institute of India, the largest manufacturer of vaccines for distribution to low-and-middle-income countries through COVAX – further exacerbated the shortfall (WHO, 2021). It is against this background that African public health leaders called for a New Public Health Order as a demand for a fundamental transformation of the global infrastructural apparatus that acknowledged 'how easily global cooperation and international solidarity can collapse' in the face of collective health threats (Nkengasong & Tessema, 2020, p. 296).

A common term to explain the systematic underinvestment in vaccine R&D, especially for preventative vaccines for infectious diseases prevalent in lowerincome countries, is that of 'market failure', that is, a lack of sufficient investment incentives due to limited purchasing power. Put differently, while intellectual property rights are widely held to be a precondition for pharmaceutical companies to generate profit on their investments in the R&D, given its uncertain outcome, this is deemed insufficient for products that would predominantly benefit those that may be unable to pay for them (cf. Birch & Muniesa, 2020; Trouiller *et al.*, 2002). As a result, much of the global vaccine 'ecosystem' – including not just vaccine developers but manufacturing facilities, suppliers, regulators and funders – has remained dominated by a few big pharmaceutical companies largely concentrated in high-income countries and a limited number of middle-income economies, such as India, Brazil and South Africa.

To be sure, the shortcomings of this system have long been challenged. Notions of 'neglected tropical diseases' and the '10/90 gap' have served to galvanize the global health community to address the inequities resulting from a R&D infrastructure that is highly geographically uneven and is based on a notion of health as something that can be abstracted and capitalized (Rajan, 2017, p. 7). And yet, high-level international policy responses to address these inequities have primarily aimed at maintaining the existing order while introducing complementary mechanisms to mitigate its impact on public health systems (Blume, 2005; Graham, 2019). We will briefly elaborate on two of the central mechanisms here – intellectual property (IP) 'flexibilities' and innovative R&D financing mechanism – to argue that whereas over the past 15–20 years these have been assigned central roles in delivering on the goals of ensuring access to the fruits of pharmaceutical R&D, they have also maintained an uneven transnational biochemical infrastructure that relies on public money to underwrite private profit.

In awarding its holder the sole right over a product or process, patents create temporary monopolies; that is, they generate economic value by restricting others from making, using or selling the patented outcome of scientific and technical labour (Gabriel, 2014). While many claim that IP protections play a vital part in stimulating pharmaceutical innovation, this raises the question of what form of innovation is stimulated and for whose benefit. Indeed, IP protection may foster forms of 'defensive innovation' that serve to sustain existing IP protection rather than address new or emerging problems (Barry, 2001, p. 212). Moreover, pharmaceutical monopolies have been repeatedly challenged for precisely the fact that they restrict access to 'global public goods' (Saksena, 2021) or a 'pharmaceutical commons' (Lezaun & Montgomery, 2015), while sustaining an uneven geography of vaccine manufacturing. One strategy to address such concerns has been the introduction of a flexible approach to IP protection. Such 'flexibilities' to international property regulations were first introduced as part of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the wake of the global HIV/AIDS crisis of the 1980s and 1990s to enable countries to respond to national public health emergencies. And yet, at the hight of the COVID-19 pandemic, Indian and South African delegations to the World Trade Organization (WTO) highlighted the insufficiency of these existing 'flexibilities' within international IP frameworks to allow the 'unhindered global sharing of technology and know-how' (WTO, 2020a, p. 2). Instead, they put forward proposals for an IP 'waiver' to temporarily suspend patent protections for COVID-19 diagnostics, vaccines and treatments, both in order to unlock idle global manufacturing capacity and to ensure equitable access to live-saving COVID-19 related products (Eccleston-Turner & Rourke, 2021). Indeed, it is worth pointing out that IP flexibilities were deemed necessary only because TRIPS institutionalized stronger worldwide IP protections in the first place.

Hyo Kang (2021) observes that when TRIPS came into force in 1995, it represented the most comprehensive multilateral agreement to ensure IP protections globally, thus providing the 'legal transnational structure for intellectual property-driven knowledge capitalism'. In practice, by establishing international norms for the protection of patents, the TRIPS agreement was most favourable for those countries with large IP-owning industries, first and foremost the United States and EU, thus helping to provide economic nationalism with a legal basis. The TRIPS 'flexibilities' that were later clarified in the Doha Declaration may have served to improve access to biomedical technologies by adding additional instruments to mitigate the impact of IP protections, such as voluntary and compulsory licensing - but, in so doing, they also helped to prop up the global IP infrastructure by protecting it from being undermined. Indeed, the key argument levelled against a COVID-19 patent waiver by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has been not only that IP protections have driven COVID-19related innovations, but that it is the licensing and transfer of technology on a voluntary basis that enabled increasing COVID-19 manufacturing capacity (IFPMA, 2020, 2021). And yet, the establishment of C-TAP, the WHO's voluntary patent pool to enable the sharing of COVID-19 technologies and know-how, has been met with stark resistance from the pharmaceutical industry (Silverman, 2020; Villemeur et al., 2021), while bilateral voluntary licensing activities have failed to produce enough vaccines to meet demand, especially from low-income countries.

Similar issues have also beset the second set of top-level strategies that are intended to foster access to pharmaceutical products: the establishment of public-private partnerships as new 'hybrid organizational models' (Lezaun & Montgomery, 2015) that use innovative financing mechanism to incentivize the R&D of pharmaceutical products in order to address the perceived problem of 'market failures'. At the forefront of such efforts has been the Vaccine Alliance GAVI, a public-private partnership that uses public (bilateral), corporate and philanthropic funding to promote pharmaceutical innovation through the creation of 'healthy market dynamics'<sup>5</sup> for particular biomedical products. In this context, GAVI first spearheaded AMCs, which have become widely considered as amongst the most innovative and effective alternative R&D financing tools. As Véra Ehrenstein and Daniel Neyland explain:

It [the AMC] was proposed as a market solution to the neglected health problems of poor countries and their people, which from this economic vantage point suffer from a lack of purchasing power. In an AMC, if a biomedical innovation like a new vaccine is developed that proves able to address a neglected health problem, it would be purchased under specific conditions for the benefit of the affected population. (Ehrenstein & Neyland. 2018, p. 69)

The promise economy created by AMCs has thus helped expand pharmaceutical markets to locales that were previously dismissed as commercially unattractive. Indeed, by subsidizing select routine vaccinations in eligible low-income countries, AMCs may offer an 'expandable solution' (Ehrenstein & Neyland, 2018) to the problem of limited access to existing vaccines. However, AMCs have arguably done little to incentivize the development of new vaccines or the establishment of greater pharmaceutical manufacturing capacity in low-or middle-income countries – in fact, by introducing additional barriers to the establishment of competitive local manufacturers, they may even have even further entrenched a model of highly geographically-concentrated R&D and manufacturing (Light, 2007; Plahte, 2012; Williams, 2012). In this new postcolonial political economy (Bump *et al.*, 2021), global vaccination infrastructures rely on donor funding and fragile notions of global solidarity while at the same time maximizing the future profit for pharmaceutical companies through the public underwriting of corporate risks in the present.

Although AMCs may thus represent an imaginative way of channelling public funds to private corporations, their celebrated status as an innovative tool that demonstrates the benefits of public-private collaboration to ensuring global access to vaccines also obscures the myriad other ways that the profitability of vaccine infrastructures has been driven – and subsidized – by national economic interests (Kang, 2021). As Nobel Prize-winning development economist Michael Kremer, who is widely credited as having first proposed the idea of AMCs, has highlighted, providing 'pull' funding aims to 'supplement, not replace, direct R&D support (i.e. 'push' funding from governments) while mitigating problems attendant with trying to pick winning projects *ex ante* under asymmetric information' (Kremer *et al.*, 2020, p. 1; see also Kremer & Glennerster, 2004). In other words, AMCs are just one in an arsenal of tools that utilize public expenditures to safeguard private financial returns and extend corporate vaccine infrastructures. And yet, the COVID-19 pandemic has also painfully highlighted what happens when the outward goals of these various tools collide.

Together with CEPI and the WHO, GAVI has led the COVAX facility which has sought to use an AMC mechanism to provide equitable access to COVID-19 technologies - especially vaccines - for low-and-middle income countries. But the international scramble for vaccine quotas has also laid bare the shortcomings of such solidarity-based distribution models as solutions to the systemic problem of unequal access, as COVAX has collided with countervailing projects more overtly pursued in the name of national interests by countries with strong pharmaceutical development and manufacturing industries (Eccleston-Turner & Upton, 2021). In the United States, the government's 'Operation Warp Speed' was launched in May 2020 to provide billions of US dollars in funding to six pharmaceutical companies not only to support R&D efforts but also the scaling up of manufacturing capacity before the efficacy of vaccine candidates had been established (Barone, 2020; Slaoui & Hepburn, 2020). With funding directed through a partnership between the US National Institutes of Health (NIH) and the US Department of Defense, 'Operation Warp Speed' has been described as 'vaguely inspired by the Manhattan project to develop the atomic bomb during World War II' (Sampat & Shadlen 2021, p. 401). Indeed, Warp Speed was explicitly billed as an 'America First' response to the COVID-19 pandemic that combined massive spending for vaccine production infrastructures with the securing of priority access to millions of vaccine doses (Stevis-Gridneff et al., 2020) - in what seems like a win-win of state-sponsored capitalism. Similarly, the UK government contributed over  $f_{,33}$  million in public funding to the late-stage development and manufacturing of the Oxford-AstraZeneca vaccine alone, in addition to having awarded grants worth millions of pounds for prepandemic R&D (Baraniuk, 2021; Cross et al., 2021). Like the United States, the United Kingdom leveraged its position to secure purchase agreements for hundreds of millions of vaccine doses (UK Government, 2021).

Both Operation Warp Speed and the UK government's response articulated an explicit national – indeed nationalist – approach to the accelerated development of vaccination infrastructure. The massive levels of intervention by the United States and other governments seem to mark a further departure from a model of pharmaceutical R&D based on private enterprise, towards one in which the state or corporate philanthropy takes on an ever-expanded role, including by underwriting the risks of investments in vaccine R&D and manufacturing through a combination of subsidy, public support for R&D, insurance, and advanced purchase agreements. It also suggests an apparent shift away from a model of 'user-led' forms of innovation that dominated thinking about innovation policy in the late twentieth century to one driven by the push of science and technology oriented by a strategic goal, echoing earlier state-led forms of R&D policy that had been dominant in the period following the Second World War (cf. Mazzucato, 2021).

For many critics, the industry's 'innovation' model has long relied on being able to derive huge profits from basic research conducted in public-funded university laboratories is nothing short of scandalous (Angell, 2004; Sampat & Lichtenberg, 2011). Using the example of Ebola vaccines, Graham (2019) shows that the most risky and time-consuming early phases of research are already effectively outsourced to the public sector whereas pharmaceutical companies only get involved in the later stages of development for the most promising vaccine candidates - putting into question the claim that vaccine producers are working under the spectre of 'market failures'. Moreover, the payment of huge amounts of public money towards incentivizing the involvement of profit-oriented pharmaceutical companies also served to 'sideswipe further opportunities for public innovation' (Graham, 2019, p. 407). In other words, it is far from clear if the significant national(-istic) investments in COVID-19 R&D indeed represent a new 'public order' of state-sponsored vaccine development, rather than the turbo-charging of existing long-hedged forms of economic nationalism - an expansion of the state mechanisms of corporate de-risking deeply embedded in the existing global R&D infrastructure, rather than the 'crowding in' of private sector expertise and investments to solve public problems, as Mazzucato (2021) proposes.

But as vaccine R&D becomes a matter of national biopolitics, this arguably further entrenches clear dividing lines between populations and forges new inclusions and exclusions – precisely because, as Mbembe and Shread (2021) argue, 'for a lack of a common infrastructure, a vicious partitioning of the globe will intensify, and the dividing lines become more intense' (p. 61). Indeed, if the COVID-19 pandemic has underscored anything, it is the shortcomings of debates that narrowly conceive of vaccine equity as a matter of unfair distribution of and access to discreet pharmaceutical objects without not also addressing the political, legal and logistical constraints that characterize the highly uneven global geographies of vaccine R&D and manufacturing (e.g. Liu *et al.*, 2020; Loembé & Nkengasong, 2021). As such, it opens up a wider set of questions about the organization of vaccine development, and the possibility of a new Global Health innovation and production system.<sup>6</sup> In the final section of this paper, we turn from the use of legal and financial ways of addressing to the need for transformations to the infrastructure of vaccine R&D and manufacturing.

# **Platforming equity**

We propose that a critical step in rethinking the current Global Health R&D and manufacturing system and the possibilities for a New Public Health Order would be the reconceptualization of vaccines not as discreet entities but as elements of more-than-national public infrastructures that are acknowledged to be 'welfare critical' (Foundational Economy Collective, 2018, p. 22). Such a move would shift attention to the complex and shifting articulations of knowledge, expertise, materials, regulations, institutions and supply chains that are mobilized in collective efforts to 'get shots into arms', as well as encourage more fine-grained analyses of those instances where such articulations creak or fail. As Clare Chandler (2019) recently noted in her call to pay attention to the 'woodwork' or infrastructural arrangements that enable the circulation of antimicrobials, doing so 'brings to the fore the arrangements of objects, people and processes that may otherwise go unobserved and yet shape possibilities for the ways things can be done and conceived' (p. 9) or, we would add, could be done and conceived differently. In the following we will thus briefly point to four lines of enquiry that further explore the notion of vaccines as infrastructures, to then suggest that such a move would also allow opening up the notion of equity - by treating it not just as a normative problem that only arises at the end, once a viable vaccine has been produced, but as the series of normative assumptions that should be embedded within the infrastructure of vaccine R&D itself.

Our first observation is that in revealing the fragmented and fragile nature of global supply chains in the pharmaceutical industry, the COVID-19 pandemic has strikingly demonstrated the complex infrastructure involved in the making of vaccines. This includes the specialist expertise of micro-, cellular and/or molecular biologists, chemists and/or biochemists, bioengineers, lab technicians who grow cell cultures and load assays, clinicians and researchers to run trials, and statisticians to analyse data. But it also requires 'stuff': specialist equipment such as flow cytometers and bioreactors - some of which are only produced by a handful of laboratories and are subject to a multitude of IP claims themselves (Ecclestone-Turner & Rourke, 2021; Gaviria & Kilic, 2021; Neubert, 2021) - as well as enzymes and lipid nanoparticles and more mundane materials including pipettes, gloves and glass vials whose production, in turn, relies on raw materials like sand. According to the WTO, a vaccine manufacturing plant typically uses 'in the region of 9,000 different materials sourced from some 300 suppliers across approximately 30 different countries' (WTO, 2020b, p. 16).

The existence and fragility of these infrastructural assemblages became visible as the need for speed and scale was confronted by limited and unevenly distributed resources, production capacities and labour (e.g. Schmidt, 2021), and by supply chains that rely on the free flow of materials across national borders (Irwin, 2021b; Martell & Rocha, 2021). Tracing the networks that connect a vaccine manufacturing facility in Macclesfield, United Kingdom, to a borosilicate glass making plant in a tiny town in southern Germany and a COVID-19 vaccination centre in Accra would highlight the resources and labour required to make COVID-19 vaccines work in specific locations. It would also highlight the shortcomings of the enduring framing of a limited availability and accessibility of vaccines as primarily a problem of demand

and markets, to shift attention to the critical role of supply in creating vaccine inequities.

Our second observation is that what counts as a working vaccine depends on the existence of a second order infrastructure or 'metrological zone' of testing, quality control and regulation (Barry, 2006). Indeed, responses to the COVID-19 pandemic have been able to draw on the metrological infrastructure of diagnostic platforms – for example in South Africa, PCR machines 'for viral HIV viral load testing enabled rapid establishment' for COVID-19 testing (Karim in Karim *et al.*, 2021). We already noted IP regulations as a critical part of the legal infrastructure that enables – and inhibits – the transnational flow of vaccines. But there are various other systems of norms, classifications and standards that the circulation of vaccines relies on.

During the COVID-19 pandemic, the constitution of this second order infrastructure, its rigour, speed, accountability and independence, have regularly become the object of dispute. For example, concerns over blood clots resulting from the use of the Oxford-AstraZeneca vaccine led the regulators in several European countries to restrict access to specific age groups, irrespective of opposing guidance from the European Medicines Agency (Kelland et al., 2021). Some commentators were quick to blame the controversy on regulator's need to 'act quickly on the basis of messy, incomplete and capricious real-world data' (Ledford, 2021). But we would argue that rather than trying to explain away such controversies by simply blaming a lack of data, they should serve as starting points to examine the contested nature of knowledge claims, the construction and management of 'risk' (Power, 2007), the shifting thresholds of what counts as 'authoritative evidence' especially in times of crisis (Kelly & McGoey, 2018) and, more broadly, what the political sociologist Béatrice Hibou (2017) has termed neoliberal bureaucratization. In the context of this complex metrological and bureaucratic system, vaccines exist not just as discrete objects but as 'informed materials' (Barry, 2005, 2020). In other words, their existence as a functioning technology is both transformed and supplemented by measurement as they circulate across these different settings, including laboratories and regulatory institutions, as well as the bodies of patients in clinical trials and following vaccination.

Third, as sociologists of technology have long recognized, the material properties of technologies have to be understood in their contexts of use (De Laet & Mol, 2000). Far from being stable entities, vaccines have varying forms of existence, through the course of the manufacturing process, in simulations, in clinical trials (where they are monitored in selected bodies), in different individual bodies (which vary with age and underlying conditions) and as they are delivered in different settings (cf. Van der Geest *et al.*, 1996; Whyte *et al.*, 2002). As Alex Nading (2015) notes, pharmaceutical chemicals, which are 'designed to create a standard immune response in a standardized human subject' (p. 357), may fail to do so in practice: [Pharmaceuticals] arrive in cities like Managua as components of standardized interventions, but they 'have changing properties depending on their associations in an everyday reality.' Released into landscapes in the name of global health, these chemicals, too, reshape local biologies. (Nading, 2017, p. 142)

Nading's observation makes it clear that human bodies have themselves become part of the biochemical infrastructure; part of the population's protection against the virus. In this context, it should be no surprise that a debate developed about whether the children should be vaccinated, and become part of the biochemical infrastructure, even if the benefits of vaccination to individual children may be limited. One might compare the role of human bodies as infrastructure to Abdoumalique Simone's (2004) account of 'people as infrastructure' that followed from his observation that 'African cities are characterized by incessantly flexible, mobile, and provisional intersections of residents that operate without clearly delineated notions of how the city is to be inhabit' (Simone, 2004). But from the point of view of the vaccine, bodies are expected to act as infrastructure in a radical different way to that envisaged by Simone. As opposed to Simone's (2004) 'incessantly flexible' infrastructure of sociability, one might say that bodies become reliable and more standardized parts of transnational biochemical infrastructures. Indeed, as Neubert (2021) argues, since mRNA vaccines rely on the body to produce the spike protein, it is the body itself that constitutes 'the globally distributed vaccine manufacturing revolution' (Neubert, 2021, Conclusion).

Fourth, building on a large body of STS literature that explicates how questions of politics and ethics are integral to the production of scientific knowledge (Barry, 2005; de la Bellacasa, 2011; Latour, 1987; Strathern & Khlinovskaya Rockhill, 2013), conceiving of vaccines as infrastructures would encourage work that seeks to render explicit the values that orient research and format its tools, objectives and objects. Consider a key difference between the mRNA COVID-19 vaccines by Pfizer/BioNTech and Oxford University/ AstraZeneca's adenovirus-vector vaccines: whereas the need to store the former at ultra-low temperatures has been blamed for limiting its useability to only a few countries worldwide, the latter's store-ability at fridge temperature meant that it was explicitly hailed as a vaccine 'made for the world' (Astra-Zeneca, 2021). What this example points to is the way that issues such as distributivity and accessibility can come to inform the way in which vaccines are designed as elements of infrastructure.

Indeed, our last observation is that novel vaccine technology platforms not only exhibit adaptability to new (variants of) pathogens, but they also have other benefits that may make them integral elements of a New Public Health Order and more-than-national and regional biochemical infrastructures. In their work on ordering practices in contemporary biomedicine, sociologists Peter Keating and Alberto Cambrosio point to the 'biomedical platform' as an assemblage of technical and organizational, material and symbolic, elements (Keating & Cambrosio, 2000, p. 346). Specifically referring to the expansion of 'technical platforms' – integrated networks of research laboratories and specialized diagnostic clinics – and their increasing integration within the traditional hospital infrastructure, Keating and Cambrosio (2000) describe these changes as both symptomatic of and further fuelling the growth of a form of *bio*medicine in which clinical practice is increasingly shaped by non-clinical specialities, especially medical biology. While our concern is not with tracing the wider transformation of contemporary medicine, Keating and Cambrosio's (2000) work is useful in pointing to the dual character of biomedical platforms as both generated and generative, as the contingent outcome of ongoing processes of transformation as well as 'the basis of change and innovation' (p. 346).<sup>7</sup>

In this light, we propose that novel vaccine technology platforms inherit a similarly dual character: health security concerns and the emergency R&D paradigm have accelerated the development of vaccine technologies that promise speed and adaptability – a flexible infrastructure that is designed in anticipation of future threats – 'just-in-case' – but can also be updated and upgraded as those threats materialize. At the same time, vaccine platforms have become key to wide-ranging changes to the way that vaccines are developed, trialled, regulated, manufactured and distributed. Platform technologies thus transform the conditions of their own existence – rather than simply compressing vaccine development timelines, these technologies contribute to the reordering of both regulatory frameworks and the existing R&D architecture.

By promising faster speed, lower costs and more flexibility and adaptability, these technologies hold significant potential to become part of a reconfigured vaccine R&D and manufacturing landscape by enabling both: quicker scaling-up but also broader *scaling-out* and a significant decentralization of vaccine manufacturing capacities. Indeed, novel vaccine platform technologies are at the heart of the Africa CDC and African Union's recently announced plans for the establishment of series of vaccine manufacturing hubs across the continent that can flexibly shift to the production of vaccines to meet routine local demands to emergency response to novel disease threats of pandemic proportions. Whereas such hubs could act as bulwarks against the dependency on fragile global supply chains, they also hold transformative potential for national economies – positive externalities that recontextualise access to biomedical products within more far-reaching strategies of national and regional development and the forging of local skills and capacities (Karim *et al.*, 2021, Sarr, 2016).

# Conclusions

Social scientists have often been sceptical about the politics of attention conjured by declarations of public health emergencies and the reconfigurations of governmental, epistemic and normative practices that follow in their wake (Caduff, 2015; Fassin, 2012; João, 2016; Kelly, 2018; Lakoff, 2015). And yet, by rendering the enduring shortcomings of the current global vaccine R&D and manufacturing system visible, the COVID-19 pandemic has also problematized the dominant models of global health innovation, the significance of IP to innovation, the reliance on advanced market commitments, and the contested role of the state. In other words, the global emergency has put to the fore questions about the kinds of vaccines that not only can, but should, be produced, by whom, where and under what conditions.

The 'New Public Health Order' is not yet in a stabilized form. Rather, it should be understood as a problematization of the existing more-than-local yet less-than-global biochemical infrastructure of vaccine R&D and manufacturing, and as an intervention in its future becoming. In this paper, we have highlighted two critical features of the existing biochemical infrastructure of vaccines and its relation to the question of equity. First, while infrastructures are often understood as spatial structures, albeit marked by instabilities, breakages, corrosion and accretions, as well as systemic inclusions and exclusions, a feature of the emerging biochemical infrastructure is that it is expected to be flexible, able to respond 'just in case' and not just 'just in time', swerving rapidly to manage the activity of emerging pathogens.

Second, whereas future work will need to pay attention to how these infrastructural transformations will play out in practice, we propose that, as least in theory, novel vaccine platform technologies may not just satisfy demands for acceleration, flexibility and perpetual pandemic readiness but also offer opportunities to 'platform' equity by upstreaming equity concerns into the design and manufacture of vaccine infrastructures. Ultimately then, this paper has argued that vaccines should not be thought of as goods that can be sold and distributed globally, nor as scalable products of a single global health market. Rather the public health value of vaccines is best understood as elements of multi-layered, more-thannational public infrastructures, that are attuned both to the dynamic evolution of pathogens and to local welfare critical needs and resources.

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#### Notes

1 'The foundational provision of goods and services [that] is welfare critical for users because providential access stunts lives and limits possibilities' (Foundational Economy Collective, 2018, p. 22).

2 On the distinctions between invention and anti-inventive and innovation see (Barry, 2001, pp. 210–213).

3 https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts.

4 World Health Organization (2016).

5 https://www.gavi.org/vaccineswork/what-advance-market-commitment-and-how-could-it-help-beat-covid-19.

6 https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334.

7 There is not the space here to interrogate the relation between the increasingly common discussion of platforms and the digital economy, and the emphasis on platforms in vaccine R&D. On the notion of 'platform capitalism'. We agree, nonetheless, with Langley and Leyshon (2017, p. 8) that the use of the term platform has computational and coding roots, but the other architectural, figurative and political understandings are bundled in and create 'broad connotations' that platforms are 'open, neutral, egalitarian and progressive'.

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